42. (Original) The pharmaceutical composition of claim 33 wherein the gel forming polymer is a water soluble salt of one or more polyuronic acids.

43. (Original) The pharmaceutical composition of claim 33 wherein the gel forming polymer is sodium alginate.

44. (Original) The pharmaceutical composition of claim 33 further comprising about 0.5% to about 20% by weight of an additional hydrophilic water soluble polymer.

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45. (Original) The pharmaceutical composition of claim 44 wherein the additional hydrophilic water soluble polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropylcellulose, polyacrylic acid, and mixtures thereof.

46. (Original) The pharmaceutical composition of claim 33 in the form of a tablet which is coated with a rapidly dissolving water soluble film forming polymer or a rapidly dissolving pharmaceutical excipient.

47-50. Cancelled

2 1-12, 14-46

Remarks

Claims 1-46 are pending. Claims 1, 16-20, 33 and 41 have been amended to recite "viscosity enhancing agent" in place of "viscolyzing." Claim 1 has also been amended to specify the swelling agent "present in an amount of from about 5% to about 50% by weight." Claim 2

has been amended to delete reference to "therapeutic drugs." Support for the amendments is found, for example, on page 17, lines 11-14. No new matter is introduced thereby.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 1-46 have been rejected as indefinite for a) reciting "viscolyzing agent" in claims 1, 16-20, 33 and 41 (and claims dependent therefrom), and b) reciting "therapeutic drugs" alongside allegedly narrower statements of the limitation. Applicants respectfully traverse the rejection for the following reasons.

Claims 1, 16-20, 33 and 41 have been amended, as the Examiner has suggested, to recite "viscosity enhancing agent" in place of "viscolyzing agent." The intent of applicant is clear, as ascertained by the Examiner, that the recited component has, as one of its functions, a function of increasing viscosity upon contact with gastric fluid, as pointed out, for example, on page 9, lines 4-7, on page 11, lines 19-21, and on page 17, lines 16-18.

Claim 2 has been amended, as the Examiner has suggested, to eliminate reference to "therapeutic drugs" as recited alongside other statements of the limitation.

Applicants respectfully submit that the instant rejections have been overcome by applicants' amendments to the claims, and that the rejection should be reconsidered and withdrawn.

Rejection Under 35 U.S.C. §103(a) Over Kuhrts (United States Patent No. 5,292,518)

Claims 1-46 have been rejected as obvious over Kuhrts. Applicants respectfully traverse the rejection for the following reasons.

Kuhrts relates to prolonged-release drug formulations, consisting essentially of "an effective dose of a biologically-absorbable drug or other therapeutic agent, a gel-forming dietary fiber, and a mineral salt which releases a physiologically-acceptable gas upon injection." (col. 4, lines 20-24). Optionally, "a physiologically acceptable acid" is provided. (col. 4, lines 25-26). Significantly, every statement of the invention of Kuhrts describes the prolonged-release

formulations therein as "consisting essentially of" particular components (gel-forming dietary fiber, biologically-absorbable drug, and a disintegrant). The transitional phrase "consisting essentially of," has the legal significance that it "excludes ingredients that materially affect the basic and novel characteristics of the claimed composition." Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569 (Fed. Cir. 1984).

Kuhrts discloses the inclusion of "polyvinylpyrrolidone (crosslinked)" in a single example, Example 2. The amount of this material is 15 mg in an 840 mg tablet, a resulting weight percentage of 1.7%. Kuhrts does not disclose or suggest the use of a swelling agent, as applicants use that term, in amounts from about 5% to about 50% by weight in any of the Kuhrts compositions. Further, there is no suggestion to one of ordinary skill in the art to modify Kuhrts by including a swelling agent in an amount of from about 5% to about 50% by weight. Without motivation to modify the prior art, there is no *prima facie* case of obviousness.

Applicants respectfully submit that the claimed invention is not obvious over Kuhrts, and request reconsideration and withdrawal of the rejection.

Rejection Under 35 U.S.C. §103(a) Over Chauhan et al. (United States Patent No. 5,597,844)

Claims 1-6 and 9-46 have been rejected as obvious over Chauhan et al. Applicants respectfully traverse the rejection for the following reasons.

Chauhan et al. relates to cimetidine granules coated with a partially hydrogenated vegetable oil, and tablets made from these granules which also include a suspending agent, surfactant, antacid, alginate. Chauhan et al. also discloses the use of "a disintegrant such as a cross-linked polymeric disintegrant" (col. 4, lines 24-28) in Examples 4-7 (Croscarmellose Sodium Type A). This material is present in amounts from about 2.4% (60 mg in a 2500 mg tablet; Example 7) to about 2.8% (60 mg in a 2115 mg tablet; Example 4).

Chauhan et al. does not include any disclosure or suggestion of using a swelling agent, as applicants have used the term, in an amount of from about 5% to about 50% by weight, as the instant claims require. Without such a motivation, a *prima facie* case of obviousness cannot be

made. Applicants respectfully submit that the claimed invention is not obvious in light of Chauhan et al., and request that the rejection be reconsidered and withdrawn.

Rejection Under 35 U.S.C. §103(a) Over Kuhrts and Chauhan et al.

For the reasons given above with respect to the references individually, the suggested combination of references also fails to make a *prima facie* case of obviousness. In particular, for a *prima facie* case of obviousness to be made, all claim limitations must be taught or suggested by the prior art. Since neither reference taken individually, nor in any combination, teaches or suggests the claimed invention, a case of *prima facie* obviousness can not be made.

Conclusion

Applicants respectfully submit that the pending claims are allowable, and request a Notice of Allowance at this time. Authorization is hereby given to charge any fees deemed to be due in connection with this Response to Deposit Account No. 50-0912.

Respectfully submitted,
TALWAR *et al.*

By: _____
George E. Heibel, Ph.D.
Reg. No. 42,648

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Ranbaxy Pharmaceuticals Inc.
600 College Road East, Suite 2100
Princeton, New Jersey 08540
Tel: (609) 720-5334
Fax: (609) 514-9779